Appendix A

Proposed and/or Adopted Genetic Legislation in Washington State between 1998 and 2002[1]

Number	Year	Title	Sponsor	Summary
SB 5298	1998		Senator Franklin	This bill protects genetic information from health insurance discrimination, and defines genetic information as information about genes, gene products, or inherited characteristics. (see SB 6663, 1998)
SB 6663	1998		Senator Franklin	This bill prohibits insurer discrimination in coverage or benefits on the basis of genetic information, and employer discrimination on the basis of genetic information. Additionally, it protects the right of an individual to refuse to disclose genetic information, and it creates a cause of action for violation of the provision. Genetic information is defined as information about inherited characteristics.
HB 1757	1999	DNA Data Base--Violent and Sex Offenders Effective Date: 7/25/99	Representative Miloscia	Enacted, 1999. Provides that every juvenile or adult convicted of a violent or sexual felony shall have blood drawn for purposes of DNA identification analysis. A purpose of the legislation is to create an expanded DNA data bank for use in law enforcement. The act amends RCW 43.43.754, and creates a new section.
HCR 4412	1999	DNA Technology	Representative Miloscia	Adopted, 1999. The resolution establishes a joint select committee on DNA identification to review the following: DNA use, DNA identification, DNA testing, DNA data banking, DNA technology, DNA research, and DNA privacy issues. After reporting its findings to the legislature, the committee expires July 1, 2000.

[1] Full text, history, and digests of the House and Senate Bills summarized in the table may be found at the Washington State Legislature's website <<http://www.leg.wa.gov>>. Specific bills are indexed at the site by date and source: e.g. SB 5298 is at: http://www.leg.wa.gov/pub/billinfo/1997-98/senate/5275-5299/5298_012297.txt.

Proposed and/or Adopted Genetic Legislation in Washington State between 1998 and 2002

Number	Year	Title	Sponsor	Summary
SB 5111	1999	Health Insurance Discrimination	Senator Franklin	This version of the bill prohibits health insurance discrimination on the basis of genetic information. It declares that a health carrier may not deny or cancel health plan coverage or vary the premiums, terms, or conditions for coverage, for an individual or a family member of an individual either 1) on the basis of genetic information, or 2) because the individual or family member of an individual has requested or received genetic services. It additionally prevents a health carrier from requesting disclosure of individual's genetic information, and it also prevents the health carrier from disclosing any genetic information about an individual without his consent.
ESSB 5111	1999	Health Insurance Discrimination		This bill is very similar to SB 5111 described above. It adds three limited situations in which a health carrier may disclose a patient's genetic information: research, internal use for family genetic counseling, and newborn screening authorized by 70.83 RCW.
HB 2491	2000	DNA--Postconviction Testing Effective Date: 6/8/00	Representative Schindler	Enacted, 2000. Allows persons sentenced to death or life imprisonment to request deoxyribonucleic acid testing of evidence in their case. This act relating to DNA testing of evidence, amends RCW 10.37.050, adds a new section to RCW 10.73, and creates new sections.
HB 2732	2000	DNA Identification System	Representative Miloscia	This bill provides for collection of blood samples for DNA identification from convicted felons. It finds that the DNA identification system is increasingly useful in the accurate investigation and prosecution of criminal offenses, and determines that it is in the public interest to expand the DNA identification system to include all convicted felons.

Proposed and/or Adopted Genetic Legislation in Washington State between 1998 and 2002

Number	Year	Title	Sponsor	Summary
HB 2861	2000	Health Care Information Definition	Representative O'Brien	This bill modifies the definition of "health care information" to explicitly include "a patient's deoxyribonucleic acid and identified sequence of chemical base pairs".
SB 6203	2000	Institutional Review Boards	Senator Fairley	This bill provides requirements for the composition of institutional review boards, and relates to health facility oversight.
SB 6284	2000	Protection of DNA Information	Senator Hargrove	This bill, as originally introduced, protects DNA identification information, specifically data collected during criminal investigations of suspects who were not convicted, or juvenile victims or offenders. As substituted in Jan., 2000 this bill sets up a DNA commission to evaluate issues relating to use and protection of DNA information.
SB 6326	2000	Insurance Transactions	Senator Franklin	This bill prevents a person's DNA from being screened for any insurance transaction.
SB 6327	2000	Genetic Discrimination	Senator Franklin	This bill prevents genetic discrimination using "information obtained from interpreting the sequence of chemical base pairs in a person's deoxyribonucleic acid". It amends RCW 49.60.
SB 6340	2000	Civil Action	Senator Franklin	This bill creates a civil action for improperly obtaining a persons DNA.
SB 6341	2000	Informed Consent	Senator Franklin	This provision requires informed consent before obtaining a person's DNA. It specifies requirements for informed consent, and it lists circumstances in which informed consent is not needed.
SB 6395	2000	DNA Technology Issues Commission	Senator Franklin	This bill establishes a commission to study issues involving deoxyribonucleic acid technology.

Proposed and/or Adopted Genetic Legislation in Washington State between 1998 and 2002

Number	Year	Title	Sponsor	Summary
ESSB 6395	2000	DNA Technology Issues Commission	Senator Franklin	In addition to establishing a commission, this bill prevents screening of a person's DNA in an insurance transaction, it prevents discrimination regarding DNA screening in employment, it requires informed consent before isolating DNA for identification purposes, and it extends the commission for five years.
SB 5207	2001	Individually Identifiable DNA Testing	Senator Hargrove	This bill relates to individually identifiable DNA testing. It redefines health care information to include "genetic test information from a person's isolated DNA and a person's DNA when obtained at the request of a health care provider or health care facility." The bill also sets up a commission to report by July 1, 2002 on issues including use and misuse of DNA and genetic information, genetic privacy, and genetic discrimination.
SB 5282	2001	DNA Use in Insurance Transactions	Senator Franklin	This bill prevents insurers from "screening" an individual's DNA. In this regard, it adds a new section to chapter 48.01 RCW.
SB 5283	2001	Discriminatory Use of DNA in Employment Matters	Senator Franklin	This bill expands on the general right to be free from discrimination in employment on the basis of "race, …sex…[or] disability", by adding a specific right to prevent employers from screening a person's DNA. It amends RCW 49.60.030.
SB 5284	2001	DNA Informed Consent	Senator Franklin	This bill requires informed consent prior to isolating DNA in a form that identifies an individual for the purposes of genetic testing. Informed consent must include specific elements, and the bill lists specific circumstances in which informed consent under this section is not required.
SB 5665	2001	Genetic Information	Senator Prentice	This bill declares that each person has a fundamental privacy interest in his or her genetic information. It also protects an individual's right to choose or refuse to release their genetic information.

Proposed and/or Adopted Genetic Legislation in Washington State between 1998 and 2002

Number	Year	Title	Sponsor	Summary
ESSB	2002	Health Care Information--DNA	Representative O'Brien	This bill amends RCW 70.02 by changing the definition of 'Health Care Information' to include a person's DNA. This bill passed the legislature in March 2002.
HB 2468	2002	An act relating to the convicted offender DNA data base	Representatives Miloscia, O'Brien and Wood	This bill expands the class of persons from whom DNA samples are taken to include persons convicted of: any felony; stalking; harassment; and communicating with a minor for immoral purposes. It also specifies that samples must be taken from persons convicted before the effective date of the act who are still incarcerated as of the effective date of the act. And it states that the method of collecting the samples is no longer limited to drawing blood only. This bill passed the legislature in March 2002.
SB 6473	2002	An act relating to the convicted offender DNA data base	Senators Hargrove, Long, Costa and Winsley	Companion bill to HB 2468

Appendix B

Summary of Comments on September 17th Draft of GTF Report. Detailed responses from GTF members are available from the SBOH office.

Name	Comments	Action Taken	Endorsement
Robin Bennett	Added comment to one recommendation; technical comments	Inserted comment as a footnote; made corrections as indicated	Yes
Phil Bereano	Several technical comments; submitted 2-page document titled "Separate Views", see attached	Made many changes as indicated; unable to make other changes without significantly changing the existing content	Yes
Wylie Burke	Suggested change in the language of one recommendation	Made change as suggested	Yes
Peter Byers	Dissented from one recommendation; submitted text for section on Subcommittee Three; one technical comment	Inserted dissent as a footnote; incorporated text into appropriate section; made change as suggested	Yes
Maureen Callaghan	No response		---
Howard Coleman	No comments on content		Yes
Amanda DuBois	No comments on content		Yes
Joe Finkbonner	No comments on content		Yes
Nancy Fisher	Added comment to one recommendation	Inserted comment as footnote	Yes
Maxine Hayes	No comments on content		Yes
Vicki Hohner	No response		---
Mellani Hughes	Dissented from one recommendation; technical comments	Inserted dissent as a footnote, made changes/corrections as suggested	Yes
Linda Lake	No comment on content		Yes
Helen McGough	Provided a reference; suggested change in the language of one recommendation	Inserted reference; made change as suggested	Yes
Robert Miyamoto	Added comments to methods and findings	Inserted comments as footnotes	Yes
Suzanne Plemmons	Technical comments	Made changes/corrections as suggested	Yes
Ree Sailors	No response		---
Julie Sando	No comments on content		Yes
Julie Sanford-Hanna	Added comment to one recommendation	Inserted comment as a footnote	Yes
C. Ron Scott	Commented on missing language from recommendations	Issue addressed in different section of report	Yes
Brenda Suiter	Technical comments	Made changes/corrections as suggested	---
Ty Thorsen	Technical comments		Yes

Separate Views

Professor Philip L. Bereano

The documentation in the peer-reviewed literature of over 200 cases of genetic discrimination a number of years ago, the passage of legislation on this topic by over 40 states in the last decade, two recent and well-publicized cases (Burlington Northern and Lawrence Labs), and an enormous literature—both scholarly and popular--testify to the reality of genetic privacy and discrimination as proper subjects of public policy. I am pleased that the Task Force is recommending some statutory amendments to address some of these issues.

These remarks are designed to explain the several footnotes indicating that, in my view, these recommendations do not go far enough. I believe that new legislation on this subject, which clearly covers employment and life insurance, as well as the health area, is necessary. I also feel that the Task Force has inadequately addressed the privacy issues inherent in the initial taking and storing of biological samples.

Currently, residents of this state are at higher risk of having their genetic data misused than are residents elsewhere. There is no reason to believe that genetic discrimination has NOT occurred here, especially since there are essentially no independent systems for reporting it (and protecting the victim) so as to provide monitoring of the situation. Since we don't look, we don't find; but that is not evidence that the problem doesn't locally exist.

Research and Healthcare Activities

There is no justification for excluding research activities from the arenas where individuals ought to be able to determine what is done with information about them. None of us exists for the purpose of providing interesting data for the furtherance of someone else's career or profit margin. No studies were provided to us indicating that respecting the genetic privacy of research subjects by requiring voluntary informed consent for the collection and use of their genetic information has inhibited research; indeed, I do not believe that there are any such studies at all.

The Task Force's approach is based on a paradigm ("the altruistic researcher") that is increasingly shown to be at variance with reality. Given the current ties between researchers—even academic researchers—and the corporate sector (via patent holdings, stock options, contracts, directorships, etc.), many researchers have a decided interest in the use of their research data that goes well beyond preparing a paper that will pass peer review. "All policymakers must be vigilant to the possibility of research data being manipulated by corporate bodies and of scientific colleagues being seduced by the material charms of industry. Trust is no defense against an aggressively deceptive corporate sector." (*The Lancet*, April 2000)

The US Office of Research Integrity, a national monitoring agency, reported that 2001 had the highest number of misconduct cases in 25 years. (*British Medical Journal* 2002; 325:182; 27 July). Violations of patient confidentiality are on the front page of the *New York Times* (see, for example, "Free Prozac in Junk Mail Draws a Lawsuit," July 6, 2002). Even prestigious local institutions such as the Fred Hutchinson Cancer Research Center have bent ethical boundaries (see, for example, "Judge: Hutch didn't reveal study's risk to patient", *Seattle Times*, Aug. 9, 2002), and researchers have left the University of Washington for completely private work rather than submit even to minimal restrictions. Furthermore, this summer, the Administration has significantly weakened the proposed HIPPA data privacy rules by eliminating critical aspects of patient control.

I strongly agree with the view stated by the Task Force that genetic information should be protected in order to bolster peoples' confidence in the health care system, assuring that individuals have no hesitation about getting the diagnoses and treatments they may need, and also minimizing barriers to their participation in bioresearch. One-third of recent survey respondents feared that genetic testing might endanger their health insurance, and thus some refused to participate in research activities; these fears lead many to decline genetic counseling (Rothenberg and Terry, *Science*, 12 July 2002).

Forensics

I cannot subscribe to the position that tissue samples taken from individuals to create an ID database should not be destroyed after the DNA code is obtained. This view flies in the face of virtually all of the literature on the subject, even literature that is not very sensitive to civil liberties concerns (see, for example, Williamson and Duncan, "DNA Testing for All," *Nature*, 418, 585-6, 2002). These samples contain a great deal of biological information over and above anything that is germane to the DNA bank. Our recommendations, in my view, ought to be more consistent with the position of the Nation's Founders who were clearly skeptical of the use of power by forces of government, and advocated many practical ways to limit government as a result. Especially at this time, when the FBI and its parent agency the Justice Department are establishing sweeping new surveillance operations with hardly a nod to civil liberties, our Task Force ought to be less trusting. Colleagues who work with the CODIS system assure me that it is under no practical oversight. The government always claims that acknowledging civil liberties makes it less efficient; but ours was never designed to be the most efficient form of governance, only the most democratic. We should recommend that the tissue samples be destroyed after the purpose for taking them (getting the unique DNA code) has been satisfied.

Appendix C

Genetic Privacy and Genetic Discrimination Matrix for Washington State

Note: The Meeting Summaries prepared after the first three GTF meetings may be helpful cross-references for many topics. These are available at http://www.doh.wa.gov/SBOH/Priorities/Genetics/genetics.htm.

	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**American's with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Encompasses/Defines Genetic Information	Yes, 'health information' is defined broadly and is generally interpreted to encompass genetic information. No. Does not specifically define *genetic information* separate from health information.	Yes, 'health care information' includes an individual's deoxyribonucleic acid and identified sequence of chemical base pairs. No. Does not specifically define *genetic information* separate from health care information.	Yes, it uses the same definition of 'health care information' as RCW 70.02. No. Does not specifically define *genetic information* separate from health care information.	Yes, it protects all readily identifiable personal information. No. Does not specifically define *genetic information* separately from other types of personal information.	Yes, **45 CFR 46** applies to all personally identifiable information used for research purposes. **21 CFR 50/56** apply to all research regulated by the FDA. No. Do not specifically define *genetic information*.	Yes, the EEOC interprets the ADA "regarded as" clause to encompass existing and pre-symptomatic genetic disorders. No. Does not specifically define *genetic information*.	Yes, WAC 284-43-720 genetic information is not a pre-existing condition without a diagnosis of the condition. No. Does not specifically define *genetic information*.	Yes, disability is broadly defined and is interpreted to encompass genetic disorders. WAC 162.22.020 No. Does not specifically define *genetic information* separate from disability.
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**American's with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Requires Authorization for the Release of Genetic Information to Third Parties Within the Health Care System	No, the revised Rule does not require that health care providers obtain a patient's consent/authorization for the release of health information for 'routine purposes' such as treatment, health care operations, and payment. Yes, Specific authorization is required for all other releases. Exceptions exist for public health, research, law enforcement, and other uses required by law.	Yes, 70.02.020 A health care provider is required to obtain written authorization from an individual for the release of any health care information to any other person. (EXCEPT as outlined in 70.02.050)	Yes, Patient consent is required for the disclosure of health care information.	Yes, it prevents state agencies, employees and contractors from selling or disclosing personal identifying information.	Yes, **45 CFR 46** requires authorization to release identifiable information, except as required by law. To obtain additional protections against compelled disclosure, researchers may apply for a federal certificate of confidentiality. **21 CFR 50** requires notification of the extent to which confidentiality of information will be protected and a notification that the FDA may inspect research records.	N/A.	Yes, requires insurers to protect patients' privacy according to existing state and federal laws.	N/A.

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	American's with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Requires Authorization to Release Genetic Information to Entities Outside of the Health Care System (banks, schools, loan agencies, etc)	Yes, requires specific authorization for disclosure (if the disclosures is for purposes other than treatment, payment, or health care operations) but HIPAA does not protect the information once it leaves the health care system if the information is released to an entity not covered by HIPAA. There are some exceptions and other laws may govern privacy in other areas.	Yes, requires specific authorization for disclosure but it does not protect the information once it leaves the health care system. There are some exceptions and other laws may govern privacy in other areas.	Yes, it requires specific authorization for disclosure of health care information.	Yes, it prohibits state agencies, employees or contractors from disclosing personal information to any party without legal authority.	Yes, **45 CFR 46** requires authorization to release identifiable information to all entities except when required by law. **21 CFR 50** requires notification of the extent to which confidentiality of information will be protected and a notification that the FDA may inspect research records.	N/A	Yes, requires insurers to protect patients' privacy according to existing state and federal laws.	N/A
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**American's with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Includes Specific Informed Consent Requirements for the Disclosure or Use of Genetic Information	No. Neither specific authorization nor informed consent is required to disclose or use health information for routine purposes such as treatment, payment, health care operations, and for selected other uses by law or for the public good. Yes. Patients must authorize all other disclosures or uses and be informed about what information will be released and for what purposes.	Yes. It requires specific authorization for all disclosures except to third party payers and other exceptions as outlined in 70.02.050. Patients must be informed about what information will be released and for what purposes.	Yes. It mandates the same authorization/consent requirements as 70.02	N/A.	Yes. **45 CFR 46** Requires consent for disclosure of any identifiable information, but does not specify genetic information. **21 CFR 50** requires informed consent for participating in research including notification of the extent to which confidentiality of information will be protected and a notification that the FDA may inspect research records.	N/A	No.	N/A.

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	American's with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Protects Human Biological Material (tissue, cells or serum) **from Unauthorized Release or Use**	No, defines health information as oral, written or electronic; does not imply or specify biological material. The assumption is that material is not health information until it is translated into oral, written, or electronic form	No, does not explicitly refer to biological material, but does cover "any information whether oral or recorded in any form or medium", which could theoretically encompass biological material.	N/A.	N/A.	Yes, **45 CFR 46** considers human biological samples from living humans stored with links to identifiers as research involving human subjects. **21 CFR 50** requires an explanation of the procedures to be followed including use of biological materials.	N/A.	N/A.	N/A
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**American's with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Regulates Access to Genetic Information by Blood or Legal Relatives	Yes. Release of health information is permitted with the individual's consent (if the individual is present) and/or if the covered entity reasonably infers consent based on medical judgment or lack of objection. Health care providers must notify patients that they have the right to agree or object to disclosure practices such as disclosure to family. (Sect. 164.510)	Yes. 70.02.050 1(e) Health care providers may orally relate an individual's health care information to family members and others with a close personal relationship to the individual without the individual's consent unless the individual has instructed the health care provider in writing not to disclose the information. RCW 70.02.130 A person authorized to consent to health care for another may also exercise the right to access and authorize disclosure of the information.	Maybe. Health carriers and insurers are required to adopt policies and procedures that conform administrative, business, and operational practices to protect an enrollee's right to privacy or right to confidential health care services granted under state or federal laws. (SB 6199 Section 5). State and federal laws allow relatives to have access to health care information.	Maybe. State agencies are required to "provide reasonable assurances that those [records] containing confidential personal information are properly safeguarded". This may protect information from release to related third parties, but it may not. No. No specific mention is made about release of or access to information to family members or related third parties.	Yes. **46.116 (a) (5) and 21 CFR 50** require that informed consent include an explanation of the extent to which confidentiality of identifiable records will be maintained. This is interpreted to include information about to whom information may be given and under what circumstances. No. There are no specific limits or guidelines regarding the release of information.	N/A	N/A	N/A

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	American's with Disabilities Act (ADA	Office of Insurance Commissioner RCW Title 48 WAC 284.43	Washington State Law Against Discrimination RCW 49.60 WAC 162
Regulates the Use of Genetic Information by Health Insurance Companies for Determining Eligibility or Setting Rates	Yes, the portability component states that genetic information may not be considered a pre-existing condition unless a patient has a diagnosis. It also provides that insurers cannot use genetic information to apply different eligibility requirements or rates to individuals within a group plan. No, it does not regulate what information an insurance company may ask for.	No, it does not generally apply to insurers. However, 70.02.045 does prohibit third party payers from releasing health care information. See next column re SB6199.	Yes, it makes insurers subject to the provisions of the UHCIA in regards to disclosure and protection of health care information, although exemptions are broader with respect to insurers activity. No, it does not regulate how the insurer can use the information in practice.	No, only applies to state governments agencies, employees and contractors.	N/A.	N/A.	Yes, insofar as defining a pre-existing condition is concerned and insofar as the rules disallow "high-risk" rate setting based on health status by health plans. (WAC 284-43-720) (RCW 48.44.23). See RCW 48.43.005 for list of exceptions to 'health plan'	Yes, addresses issues related to discrimination based on status in a protected class (e.g. disabled)
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**American's with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Regulates the Use of Genetic Information by Life Insurance Companies for Determining Eligibility or Setting Rates	No, it only applies to health insurance.	No, it only applies to health insurance.	No, it only applies to health insurance.	No, only applies to state governments agencies, employees and contractors.	N/A.	N/A.	Yes. May allow use of genetic information to deny a life insurance policy but prohibits the cancellation of a policy based on new information obtained after the policy was issued. Allows the use of genetic information to set rates but not change them. WAC 284.84.100	Yes, addresses issues related to discrimination based on status in a protected class (e.g. disabled)

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	American's with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Regulates Use of Genetic Information by Other Entities (e.g. banking, housing, schools) for Determining Eligibility or Setting Rates	No, does not apply to genetic information outside of the health care system or its contractors.	No.	No, it only applies to health insurance.	No, only applies to state governments agencies, employees and contractors.	N/A.	N/A	N/A	Yes, addresses issues related to discrimination based on status in a protected class (e.g. if someone with a genetic predisposition was perceived as or treated as disabled, they would be protected)
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**American's with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Regulates Use of Genetic Information by Employers for Determining Employment Status or Health Insurance Benefits Eligibility	Yes, insofar as an employer cannot deny an employee health care benefits offered to other employees based on genetic information. No, it does not specifically regulate the use of genetic information for employment decisions.	N/A.	N/A.	No it does not specifically regulate use, it does regulate the collection and release of readily identifiable information if the employer is a state agency or contractor. It does not regulate use of genetic information for employment decisions.	N/A.	Yes, requires employers to make reasonable accommodations for person with disabilities and disallows them from requiring medical/genetic testing that is not job-related or consistent with business necessity.	No.	Yes, addresses issues related to discrimination based on status in a protected class (e.g. if someone with a genetic predisposition was perceived as or treated as disabled, they would be protected)

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	American's with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Protects Asymptomatic People with a Genetic Susceptibility from Unauthorized Disclosure of Genetic Information and/or Discrimination Based on Genetic Status	Yes, individuals with a record of a genetic susceptibility are protected from the disclosure of that information for non-routine purposes. Yes, it protects an individual from health insurance discrimination as described above. No, it does not protect from employment or other discrimination.	Yes, individuals with a record of a genetic susceptibility are protected from the disclosure of that information if it is part of their health care/medical record; except as outlined in 70.02.050. No, it does not protect against employment or other discrimination.	No, it does not regulate health insurance eligibility requirements, however it mandates that those requirements be disclosed prior to enrollment. (pre-existing conditions are defined and regulated elsewhere)	Maybe, it limits "the collection of personal information to that reasonably necessary for purposes of program implementation, authentication of identity, security, and other legally appropriate agency operations." No, it does not protect against employment or other discrimination.	Yes, **46.116 (a) (5) and 21 CFR 50** requires that informed consent include an explanation of the extent to which confidentiality of identifiable records will be maintained. This is interpreted to include information about to whom information may be given and under what circumstances. No. There are no specific limits or guidelines regarding the release of information.	Yes, the EEOC interprets the "regarded as" clause to be protective of persons with pre-symptomatic genetic conditions.	Yes, by limiting the use of genetic information without a diagnosis in the determination of a pre-existing condition. (WAC 284-43-720)	Yes, definition of disability includes conditions that are perceived to exist whether or not they exist in fact.
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**American's with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Protects Symptomatic People with a Genetic Disorder from Unauthorized Disclosure of Genetic Information and/or Discrimination Based on Genetic Status	Yes, individuals with a record of a genetic susceptibility are protected from the disclosure of that information for non-routine purposes. Yes, it protects an individual from health insurance discrimination as described above. No, it does not against employment or other discrimination.	Yes, individuals with a record of a genetic susceptibility are protected from the disclosure of that information if it is part of their health care/medical record; except as outlined in 70.02.050. No, it does not protect against employment or other discrimination.	No, it does not regulate health insurance eligibility requirements, however it mandates that those requirements are disclosed prior to enrollment. (pre-existing conditions are defined and regulated elsewhere)	Maybe, it limits "the collection of personal information to that reasonably necessary for purposes of program implementation, authentication of identity, security, and other legally appropriate agency operations. No, it does not protect against employment or other discrimination.	Yes. **46.116 (a) (5) and 21 CFR 50** requires that informed consent include an explanation of the extent to which confidentiality of identifiable records will be maintained including information about to whom information may be given and under what circumstances. No. There are no specific limits or guidelines regarding the release of information. N/A to discrimination issues.	Yes, an individual with a disability under the ADA is "a person who has a physical or mental impairment that substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment."	Yes, to the extent that the disease is not classifiable as a pre-existing condition. (WAC 284-43-720)	Yes, definition of disability includes conditions that are perceived to exist whether or not they exist in fact.

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	American's with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Regulates the Genetic Testing of Minor Children	No. HIPAA provides for state laws to control minors' rights where applicable.	N/A Other RCW13.64.060 gives emancipated minors the right to give informed consent for health care services.	N/A	N/A	Yes. **45 CFR46 and title 21** contain special provisions for research involving children. No. Does not refer directly to genetic testing.	N/A	Other: The Regence Group laboratory policy (9/15/99) regarding genetic testing: genetic testing in children to confirm symptoms or predict adult onset diseases is not medically necessary unless direct medical benefit is contingent upon the test result.	N/A
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**American's with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Regulates Use and or Disclosure of Genetic Information under Circumstances Related to Adoption	No. There are no restrictions placed on the use of health information in adoption. The only reference made to adoption limits an insurers ability to impose pre-existing condition exclusions on adopted children.	No. There are no provisions in this law regarding the use of genetic information in the adoption process. Other: RCW 26.33.350 mandates that all persons, firms, societies, associations, corporations and state agencies involved in an adoption disclose all known and available medical information to the adoptive parents.	N/A	Maybe. Requires state agencies to provide reasonable assurances that confidential personal information is properly safeguarded. State agencies dealing with adoptions fall under the purview of this EO. No. There is no mention of the adoption process.	N/A	N/A	N/A (?)	N/A (?)

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient's Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46[ψ] 21 CFR 50 21 CFR 56	American's with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Regulates Release of and Access to Genetic Information Held by Entities Outside of the Health Care System	No. Does not address the protection of health information pursuant to its release to uncovered entities (health oversight agencies, courts, law enforcement, etc). Other federal laws exist in some areas that may apply to these entities, e.g. FERPA regulates privacy of educational records in K-12 schools.	No. Does not pertain to the use or disclosure of health care information once it has been disclosed by a health care provider to a third party outside the health care system (law enforcement, courts, public health agencies, etc. Yes. This law addresses the parameters for the release of information in research and by third party payors.	No. Has the same limitations as RCW 70.02	Yes, a state agency, before contracting with an outside entity, must ascertain that the contractor has protections in place and will not allow or make unauthorized disclosures of the information. However, it does not provide specific protections that follow the information upon its release to any other entity.	Yes. **46.116 (a) (5)** requires all agencies receiving federal funds or regulated by a federal agency for research to use informed consent procedures that include an explanation of the extent to which confidentiality of identifiable records will be maintained. No. There are no specific limits or guidelines regarding the release of information.	N/A	N/A	N/A
	Health Information Portability and Accountability Act (HIPAA)*	**Washington State Uniform Health Care Information Act RCW 70.02**	**Patient's Bill of Rights SB 6199**	**Governor's Executive Order on Privacy EO 00-03**	**45 CFR 46 21 CFR 50 21 CFR 56**	**American's with Disabilities Act (ADA)**	**Office of Insurance Commissioner Rules**	**Washington State Law Against Discrimination RCW 49.60 WAC 162**
Includes Exceptions for Research	Yes. 164.512 (i) allows disclosure of health information for research with appropriate waiver and IRB or other oversight board approval. 164.502 (d) provides guidelines for de-identifying protected health information	Yes. 70.02.050 1(g) allows disclosure of health care information for research without consent if approved by an IRB.	**N/A**	N/A	Yes, some research may be exempt from IRB review. For example, privately funded research that is not regulated by a federal agency is not required by federal law to follow federal rules and guidelines. Also, some federally funded research may be exempt if it meets specific criteria. (See the April 12 meeting summary for more detail)	N/A	N/A	N/A

	Health Information Portability and Accountability Act (HIPAA)*	Washington State Uniform Health Care Information Act RCW 70.02	Patient Bill of Rights SB 6199	Governor's Executive Order on Privacy EO 00-03	45 CFR 46 21 CFR 50 21 CFR 56	American's with Disabilities Act (ADA)	Office of Insurance Commissioner Rules	Washington State Law Against Discrimination RCW 49.60 WAC 162
Regulatory Oversight and/or Enforcement and Penalties for Violations	Yes. The Health and Human Services Office for Civil Rights (OCR) enforces the HIPAA privacy rules. OCR relies on reports and formal complaints regarding violations; a formal enforcement rule is pending. OCR investigates claims of violations and seeks 'informal' resolutions of noncompliance. If an informal resolution cannot be found, OCR may apply civil monetary fines or work with the Justice Department to seek criminal prosecution. Civil monetary penalties are $100 per violation and capped at $25,000 per year. Criminal fines range from $50.000 - $250,000 and prison terms range from 1 to 10 years.	Yes. Provides for civil remedies for non-compliance to RCW 70.02. There is no oversight/regulatory body; claims of violations must be tried in court. The court may order actual damages but not incidental or consequential damages. Other: RCW 42.48.050 unauthorized disclosure of personally identifiable information by a researcher who obtained the information from a state agency is a gross misdemeanor subject to fines up to $10,000 for each violation.	Yes. Permits individuals to sue violators; an independent review process may be requested.	Yes. Each state agency appoints a designee to receive and process citizen complaints regarding privacy violations. A representative from the governor's office oversees this EO and handles complaints not addressed to specific agencies.	Yes. Institutional Review Boards monitor compliance with federal and local regulations. IRBs rely on internal and external review and inspection of research proposals and reporting of violations by research subjects or others. Penalties include fines, suspension of research activities and suspension of federal funding for research involving humans. The FDA inspects entities regulated by the FDA for compliance with FDA regulations.	Yes. The Equal Employment Opportunities Commission is the regulatory body for the ADA. The EEOC relies on employees or others to report violations. The EEOC investigates reported violations and may sue violators in court.	Yes. The OIC receives and investigates reports of violations and can levy fines on violators.	Yes. The WA State Human Rights Commission is the regulatory body for RCW 49.60. The WSHRC receives and investigates complaints. The WSHRC may hold hearings and subpoena witnesses. If WSHRC efforts fail to remedy the problem, the matter may be sent to the Attorney General for litigation before the Administrative Law Judge.

*Other resources: 1) Health Information Administration "HIPAA Policy Guide Matrix" at http://depts.washington.edu/hia under the "more information" section. 2) Comparative Health Privacy Law Matrix, a draft is available in the GTF meeting materials for February 25, 2002.

Appendix D

Glossary

This glossary lists terms that are either used in the Genetics Task Force (GTF) Report or may be useful in understanding some of the issues discussed in the report. Where applicable, the first definition listed under a term is the definition adopted by the GTF and the definition used throughout the report. Subsequent definitions for each term are provided as a supplemental resource.

Anonymous

1) Unidentified/unidentifiable.

2) The National Bioethics Advisory Committee describes anonymous biological material as "*Unidentified specimens:* For these specimens, identifiable personal information was not collected or, if collected, was not maintained and cannot be retrieved by the repository." And "*Unidentified samples:* Sometimes termed "anonymous," these samples are supplied by repositories to investigators from a collection of unidentified human biological specimens."[2]

Anonymized

1) Identifying information has been removed and is no longer associated with the information.

2) The National Bioethics Advisory Committee describes anonymized biological material as "*Unlinked samples:* Sometimes termed "anonymized," these samples lack identifiers or codes that can link a particular sample to an identified specimen or a particular human being."[3]

Confidentiality

1) This term is sometimes confused with the term "privacy"; however "confidentiality" is not the same thing as "privacy." "Confidentiality" is characterized by an organizational or professional *responsibility* to protect private information; e.g. a physician has a responsibility to keep a patient's personal health information confidential. "Privacy" is an individuals' *right* to have information remain secret; e.g. a patient has a right to keep personal health information from being disclosed to others or made public.

2) Black's Law Dictionary Definition: Entrusted with the confidence of another or with his secret affairs or purposes; intended to be held in confidence or kept secret.

3) Limited access to or limited disclosure of certain information. Access or disclosure is governed by statute, rule, or case law.

[2] http://bioethics.georgetown.edu/nbac/pubs.html "Research Involving Human Biological Materials: Ethical Issues and Policy Guidance", accessed 3/26/02.
[3] Ibid

De-Identified

1) HIPAA regulations stipulate that 18 individual identifiers must be removed from health information to 'de-identify' it. These include: name of patient, relatives, or employer; address; all elements of dates (except year) for dates directly related to an individual including birth date, admission date, discharge date, date of death and all ages over 89; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate or license numbers; vehicle identifiers and serial numbers, including license numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including voice and finger prints, full face photographic images and comparable images; any other unique identifying number, characteristic, or code.[4]

Deoxyribonucleic Acid (DNA)

1) A nucleic acid that constitutes the genetic material of all cellular organisms and the DNA viruses; DNA replicates and controls through messenger RNA the inheritable characteristics of all organisms. A molecule of DNA is made up of two parallel twisted chains of alternating units of phosphoric acid and deoxyribose, linked by crosspieces of the purine bases and the pyrimidine bases, resulting in a right-handed helical structure, that carries genetic information encoded in the sequence of the bases.[5]

Disability

1) The Washington State Human Rights Commission (162 WAC) defines "disability" as "the presence of any sensory, mental, or physical disability" and "the presence of any sensory, mental, or physical disability" includes, but is not limited to, "circumstances where a sensory, mental or physical condition: a) is medically cognizable; b) exists as a record or history; c) is perceived to exist whether or not it exists in fact.

2) The American's with Disabilities Act (ADA) defines "a person with a disability" as an individual who:
   - Has a physical or mental impairment that substantially limits one or more major life activities;
   - Has a record of such an impairment; or
   - Is regarded as having such an impairment

   A major life activity includes: functions such as caring for oneself; performing manual tasks; walking; seeing; hearing; speaking; breathing; learning; and working.

[4] From: Smith, K./Murphy, G., HIPAA policy development guide, University of Washington Health Information Administration, 2001; http://depts.washington.edu/hia.

[5] http://www.academicpress.com/inscight/04221999/DNA1.htm, accessed 3/26/02

Discrimination

1) Black's Law Dictionary: ...A failure to treat all alike under substantially similar conditions

Emancipated Minor

1) RCW 13.64 010 states that "any minor who is sixteen years of age or older and who is a resident of this state may petition in the superior court for a declaration of emancipation." RCW 13.64.060 defines the power and capacity of emancipated minor in the following way:

(1) An emancipated minor shall be considered to have the power and capacity of an adult, except as provided in subsection (2) of this section. A minor shall be considered emancipated for the purposes of, but not limited to:

(a) The termination of parental obligations of financial support, care, supervision, and any other obligation the parent may have by virtue of the parent-child relationship, including obligations imposed because of marital dissolution;

(b) The right to sue or be sued in his or her own name;

(c) The right to retain his or her own earnings;

(d) The right to establish a separate residence or domicile;

(e) The right to enter into nonvoidable contracts;

(f) The right to act autonomously, and with the power and capacity of an adult, in all business relationships, including but not limited to property transactions;

(g) The right to work, and earn a living, subject only to the health and safety regulations designed to protect those under age of majority regardless of their legal status; and

(h) The right to give informed consent for receiving health care services.

(2) An emancipated minor shall not be considered an adult for: (a) The purposes of the adult criminal laws of the state unless the decline of jurisdiction procedures contained in RCW 13.40.110 are used or the minor is tried in criminal court pursuant to *RCW 13.04.030(1)(e)(iv); (b) the criminal laws of the state when the emancipated minor is a victim and the age of the victim is an element of the offense; or (c) those specific constitutional and statutory age requirements regarding voting, use of alcoholic beverages, possession of firearms, and other health and safety regulations relevant to the minor because of the minor's age.

Genetic Characteristic

1) The GTF did not adopt a specific definition for this term. Several state laws offer different definitions of the term "genetic characteristic." For example:

South Carolina law (S 535) defines 'Genetic characteristic': Any scientifically or medically identifiable gene or chromosome, or alteration thereof, which is known to be a cause of disease or disorder or determined to be associated with a statistically increased risk of development of a disease or disorder and which is asymptomatic of any disease or disorder.

California law (SB 654) defines "Genetic characteristic": any scientifically or medically identifiable gene or chromosome, or combination or alteration thereof, that is known to be a cause of a disease or disorder in a person or his or her offspring, or is determined to be associated with a statistically increased risk of development of a disease or disorder, or inherited characteristics that may derive from the individual or family member, that is presently not associated with any symptoms of any disease or disorder."

Genetic Discrimination

1) Differential treatment of an individual or class of individuals based on genetic information. Generally used to refer to adverse or unfair discrimination in employment or health, life and disability insurance.

Genetic Information

1) Information about inherited characteristics. Genetic information can be derived from a DNA-based or other laboratory test, family history, or medical examination.[6]

2) Both HIPAA (29 USC Sec. 1181(b)) and WAC 284-43-720 state that "genetic information" shall not be treated as a pre-existing condition in the absence of a diagnosis of the condition related to such information.

3) Previously proposed legislation in Washington State included the following definitions for "genetic information":

   1998 SB 5298: Information about genes, gene products, or inherited characteristics.

   2001 SB 5282 & 5283: This legislation included no use of the term "genetic information" instead its focus narrowed to discuss DNA specifically, e.g. it used the language "screen a person's DNA" in which "screening" meant to obtain a person's DNA and identify a sequence of chemical base pairs or interpret data from DNA analysis.

   2001 SB 5665: Information about genes, gene products, or inherited characteristics, that may derive from an individual or family member of such individual and includes but is not limited to information derived from genetic tests and information about a request for or the receipt of genetic services by such individual or family member of such individual. "Genetic information" also includes information about the occurrence of a disease or disorder in family members.

4) Other state's definitions and case law definitions include:

   Oregon's definition: "Genetic information" means information about an individual or an individual's blood relatives obtained from a genetic test.

[6] This definition is based on the definition of "genetic information" in SB 6663 proposed in 1998. The GTF replaced the term "genetic test" with "DNA-based or other laboratory test."

South Carolina's definition: "Genetic information" means information about genes, gene products, or genetic characteristics derived from an individual or a family member of the individual. 'Gene product' is a scientific term that means messenger RNA and translated protein. For purposes of this chapter, 'genetic information' shall not include routine physical measurements: chemical, blood, and urine analysis, unless conducted purposely to diagnose a genetic characteristic; tests for abuse of drugs; and tests for the presence of HIV".

Case law: This appeal involves the question of whether a clerical or administrative worker who undergoes a general employee health examination may, without his knowledge, be tested for highly private and sensitive medical and genetic information such as syphilis, sickle cell trait, and pregnancy.[7]

Genetic Test

1) The analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical purposes. Such purposes include predicting risk of disease, identifying carriers, and establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn and carrier screening, as well as testing in high-risk families, are included. Tests for metabolites are covered only when they are undertaken with high probability that an excess or deficiency of the metabolite indicates the presence of heritable mutations in single genes. Tests conducted purely for research are excluded from the definition, as are tests for somatic (as opposed to heritable) mutations, and testing for forensic purposes.[8]

2) The analysis of human DNA, RNA, chromosomes, proteins, or certain metabolites in order to detect disease-related genotypes or mutations. Tests for metabolites fall within the definition of "genetic tests" when an excess or deficiency of the metabolites indicates the presence of a mutation or mutations. The conducting of metabolic tests by a department or agency that are not intended to reveal the presence of a mutation shall not be considered a violation of this order, regardless of the results of the tests. Test results revealing a mutation shall, however, be subject to the provisions of this order.[9]

3) The analysis of chromosomes, genes, and/or gene products to determine whether a mutation is present that is causing or will cause a certain disease or condition. It does not involve treatment for disease, such as gene therapy, although test results can sometimes suggest treatment options." The report also defines *gene testing* as "examination of body fluid or tissue for the presence of altered or abnormal amounts of a protein, chemical, chromosome, or gene that indicate the presence or absence of genetic disease." A definition of *predictive gene tests* is also provided: "Predictive gene tests: tests to identify

[7] Norman-Bloodsaw v. Lawrence Berkeley Laboratory 135 F.3d 1260 C.A.9 (Cal.), 1998.
[8] NIH Task Force on Genetic Testing
[9] President Clinton's Executive Order To Prohibit Discrimination in Federal Employment Based on Genetic Information

gene abnormalities in a healthy person that may make them susceptible to certain diseases or disorders.[10]

4) A laboratory test or other scientifically or medically accepted procedure for determining the presence or absence of genetic characteristics in an individual.[11]

Genomics

1) The study of genes and their function. Recent advances in genomics are bringing about a revolution in our understanding of the molecular mechanisms of disease, including the complex interplay of genetic and environmental factors. Genomics is also stimulating the discovery of breakthrough healthcare products by revealing thousands of new biological targets for the development of drugs, and by giving scientists innovative ways to design new drugs, vaccines and DNA diagnostics. Genomics-based therapeutics include "traditional" small chemical drugs, protein drugs, and potentially gene therapy.[12]

2) Genomics is operationally defined as investigations into the structure and function of very large numbers of genes undertaken in a simultaneous fashion. There are three types of genomics: structural, functional and comparative.[13]

Health Care Information

1) Any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care including a patient's deoxyribonucleic acid and identified sequence of chemical base pairs. The term includes any record of disclosures of health care information.[14]

Health Information

1) Any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present or future physical or mental health or condition of an individual or the provisions of health care to an individual or the past, present, or future payment for the provision of health care to an individual.[15]

Human Subject

1) Two federal regulations define “human subject”:

[10] The Secretary’s Advisory Committee on Genetic Testing; http://www4.od.nih.gov/oba/sacgt/gtdocuments.html, Public Consultation on Oversight of Genetic Tests, accessed 3/26/02
[11] South Carolina law (S 535)
[12] http://genomics.phrma.org/lexicon/g.html and http://www.ornl.gov/TechResources/Human_Genome/glossary/glossary_g.html
[13] http://genomics.ucdavis.edu/what.html
[14] Washington State Uniform Health Care Information Act RCW 70.02
[15] Health Information Portability and Accountability Act (HIPAA)

An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.[16]

A living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.[17]

Informed Consent (Health Care)

1) If a patient while legally competent, or his representative if he is not competent, signs a consent form which sets forth the following, the signed consent form shall constitute prima facie evidence that the patient gave his informed consent to the treatment administered and the patient has the burden of rebutting this by a preponderance of the evidence:

(1) A description, in language the patient could reasonably be expected to understand, of:

(a) The nature and character of the proposed treatment;
(b) The anticipated results of the proposed treatment;
(c) The recognized possible alternative forms of treatment; and

(d) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment;

(2) Or as an alternative, a statement that the patient elects not to be informed of the elements set forth in subsection (1) of this section.

Failure to use a form shall not be admissible as evidence of failure to obtain informed consent.[18]

Informed Consent (Research)

1) Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

[16] 21 CFR 50 Sec. 50.3
[17] 45 CFR 46
[18] RCW 7.70.060

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) The research could not practicably be carried out without the waiver or alteration; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.[19]

Law

1) A rule of conduct or action prescribed or formally recognized as binding or enforced by a controlling authority: a) A command or provision enacted by a legislature, also statute; b) Something (as a judicial decision or administrative rule) authoritatively accorded binding or controlling effect in the administration of justice.[20]

2) Includes statutes, regulations, constitutions, common law and judge-made law (judicial opinions). Black's Law Dictionary defines law as: "That which is laid down, ordained, or established. That which must be obeyed and followed by citizens, subject to sanctions or legal consequences."

[19] Section 46.116 of the 45 CFR 46 describes general requirements of informed consent in research. http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm
[20] http://www.lawyers.com/lawyers-com/content/glossary/glossary.html accessed 3/26/02

Minor

1) RCW Title 26 Domestic Relations Chapter 26.28 defines 'age of majority'. 26.28.010 reads: "Except as otherwise specifically provided by law, all persons shall be deemed and taken to be of full age for all purposes at the age of eighteen years."

Privacy

1) This term is sometimes confused with the term "confidentiality." "Privacy" is an individual's *right* to have information remain secret, e.g. a patient has a right to keep personal health information from being disclosed to others or made public. "Confidentiality" is characterized by an organizational or professional *responsibility* to protect private information, e.g. a physician has a responsibility to keep a patient's personal health information confidential. Privacy, unlike confidentiality, is constitutionally based.

2) A constitutional or common law right to protect information that would be highly offensive to a reasonable person if it were disclosed. Courts have broadly characterized the right to privacy as a right to confidentiality and autonomy-the right to be let alone.

3) Black's Law Dictionary Definition: Right to privacy: The right to be let alone, the right of a person to be free from unwarranted publicity.

4) A person's right to keep information about him/herself from being disclosed to others.

Regulation/Rule

A general term, meaning a provision adopted by a governmental entity under the authority granted to the entity by the legislature in statute or the constitution. In Washington State, these are called the Washington Administrative Code (WACs). At the Federal level the term is Code of Federal Regulations (CFRs). An example is HIPAA. HIPAA is a federal legislative act, which is codified in statute. Under the statutory authority of HIPAA, the Department of Health and Human Services promulgated a series of Rules, one of which is the Privacy Rule. A rule is enforceable law, however its legal effect may be challenged on a variety of grounds, both procedural and substantive. Black's Law Dictionary definition of rule is: "An established standard, guide, or regulation."

Appendix E

Genetics Task Force Subcommittee One Report

Subcommittee Title: Use of Genetic Information in Health Care
Subcommittee Chair: C. Ron Scott
Subcommittee Members: Robin Bennett, Robert Miyamoto, Maureen Callaghan, Julie Sanford-Hanna
Date of Report: August 14, 2002

Part I Diagnosis of Symptomatic Conditions

Background

DNA analysis is used routinely in the medical laboratory to identify alterations in genes that are responsible for disease states. It is routine for physicians to request DNA analysis of blood samples from children with mental retardation who are suspected of having the Fragile-X syndrome, from males with symptoms of Duchenne muscular dystrophy, from persons with a clotting disorder, or from adults with muscle and neurologic changes suggestive of a genetic condition. The introduction of DNA testing has simplified the medical diagnosis of these and other conditions that in the past may have involved anesthesia, muscle biopsies, or expensive and laborious testing by other means. The committee believes that the use of DNA testing for medical diagnosis of symptomatic individuals is appropriate and falls within the general realm of laboratory testing for medical reasons. Although the charge of the GTF was to focus on DNA analysis and its potential impact on individual privacy, the technologies of genetic analysis involve an expanded array of methods. Therefore we will use the term "genetic test" to include the analysis of DNA, RNA, Chromosomes, proteins or other gene products to detect disease-related genotypes, mutations or karyotypes for clinical purposes or phenotype prediction.

The incidence of discriminatory actions based upon genetic information

Findings

1. In reviewing material related to genetic testing for medical diagnostic purposes, the committee could find no examples of discrimination that had occurred by the use of genetic testing.
2. As heard by the GTF on February 25, the Washington State Human Rights Commission is aware of the potential for discrimination but has not received complaints resulting from the use or generation of genetic information for diagnostic health care purposes.
3. Furthermore, the committee finds that genetic testing is an efficient and cost-effective modality for accurately diagnosing genetic disorders.

Conclusions

1. The committee could find no evidence of discrimination based on genetic testing for individuals with symptomatic disorders, but rather finds the technology appropriate for medical diagnostic purposes.

Strategies to safeguard civil rights and privacy related to genetic information

Findings

1. The committee finds that the current laws and regulations regarding privacy of medical records are in place and are covered by hospital policy, Washington state statue, and national HIPAA regulations.
2. Furthermore, individuals symptomatic for a genetic disorder may have protection under the Americans with Disability Act.

Conclusions

1. The committee concludes that information obtained by genetic testing for symptomatic conditions should become part of the medical record, similar to other testing that would be performed for medical diagnosis.

Remedies to compensate individuals for inappropriate use of genetic information

Findings

1. The committee finds that the current legal tort system exists for compensation of individuals for the inappropriate use of medical information.

Conclusions

1. The committee concludes that no additional safeguards are necessary for this category of genetic testing.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

Findings

1. The committee finds that adequate incentives exist within the medical research community to develop genetic testing as an efficient and cost-effective method of diagnosing medical conditions.
2. The committee was concerned that the issuing of patents for specific DNA sequences may interfere with basic research and the useful development of genetic tests for clinical purposes.

Conclusions

1. As the technology improves, genetic testing will also be introduced into the public health system as an adjunct to newborn screening for treatable genetic diseases. This will promote and assist the safety and welfare of young children detected with treatable disorders.
2. The committee is supportive of this use of genetic testing for the benefit of public health.

Part II Use of Genetic Information for Reproductive Decisions

Background

Genetic technology is a powerful tool in the arena of reproductive medicine. In general, two categories of genetic testing exist for this purpose: (1) identification of pregnant couples at risk for a genetic disease that will cause severe disease in a future newborn; and (2) utilization of genetic technology in pregnancies at high risk for a severe genetic condition. An example of the first scenario is represented by a recommendation by the American College of Obstetrics and Gynecology that pregnant couples be screened for a battery of mutations that are associated with cystic fibrosis. The identification of a mutation in an asymptomatic pregnant woman would lead to the testing of the father of her child. If both were found to be carriers of a gene for cystic fibrosis, genetic counseling would be offered and prenatal testing of the fetus would be a voluntary option. The second scenario involves a couple who have previously given birth to a child with a serious genetic condition for which genetic technology can identify whether the current pregnancy is affected. The couple would be offered genetic testing as a part of genetic counseling to allow them to make a personal reproductive decision. In this situation, genetic testing is appropriate, low risk for mother and fetus, and can accurately distinguish an unaffected from an affected fetus. In this scenario, genetic testing is voluntary on the part of the couples at risk and offers a means for obtaining accurate information at minimal risk and cost, and with a high degree of accuracy.

The incidence of discriminatory actions based upon genetic information

Findings

1. The committee finds that there is little, if any, risk of discrimination based upon the use of genetic technology in the above scenarios.
2. The testing of couples or fetuses is always voluntary, done with informed consent, and information is maintained in the medical records of the individuals requesting the testing.
3. The committee reaffirmed the right of individuals to seek genetic counseling and appropriate genetic testing when they are at risk for transmitting a serious genetic disorder; and the rights of the child born with a genetic condition to be free from discrimination because of any current or future disability.

Conclusions

1. The committee concludes there is no need for legislation to expand protection of personal privacy in the area of prenatal genetic testing.

Strategies to safeguard civil rights and privacy related to genetic information

Findings

1. The committee finds that prenatal Genetic information that is contained within hospital or medical records comes under the purview of protection by hospital policy, Washington state statue, and federal HIPAA regulations.

Conclusions

1. The committee finds that risk of inappropriate use of the genetic information is the same as for other medical testing performed voluntarily for individuals.
2. The committee concludes there is no necessity to expand this protection.

Remedies to compensate individuals for inappropriate use of genetic information

Findings

1. The committee concludes that any breech of confidentiality by the above facilities would lend itself to tort action by the legal profession and censure by the appropriate medical oversight bodies or licensing bureaus of Washington State.

Conclusions

1. The committee concludes there is no necessity to expand this protection.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

Findings

1. The committee finds that active research is being performed within the medical community to expand genetic testing as an aid for reproductive health of mother and fetus.
2. There exists funding from government and private agencies to expand this field of endeavor.
3. Techniques are being developed that will use extremely small samples of amniotic fluid, maternal blood, or fetal cells to identify genetic alterations that will detect infectious agents or serious genetic conditions.

Conclusions

1. The committee concludes there is no need for legislation to protect individual privacy in this particular arena. Adequate safeguards exist within the research community (IRBs), Washington state law, and HIPAA regulations.

Part III Predictive Identification of Genetic Risk Factors for Late-Onset Diseases

Background

In certain instances, genetic testing can identify genetic predisposition to disease prior to the onset of clinical symptoms. There are three types of situations relevant to this issue. The first situation occurs in the testing of young children at high risk to develop a serious disorder for which intervention may be available. An example would be a child born into a family in which there exists a previous child diagnosed with cystic fibrosis. The second infant may be asymptomatic, but accurate genetic testing would allow for the identification of that infant as affected or unaffected with cystic fibrosis. If affected, appropriate intervention strategies would begin at the earliest time to help prevent clinical complications. Similar scenarios exist for the recognition of boys born into a family with Duchenne muscular dystrophy, or a young child born into a family at risk for a genetic disease for which there is available therapy. In this case the issues would be the same as those described in the section related to Diagnosis of Symptomatic Conditions. The second category of predictive testing is more complicated. There exist a number of disorders with clinical symptoms that present in adulthood, but which can be predicted to occur prior to symptoms with a finite probability if an individual carries a particular

form of the gene responsible for the disorder. Examples include the predilection for breast cancer in women who carry an abnormality of the BRCA1 or BRCA2 gene, or the predilection for neurological degeneration around the age of 40 in individuals with an abnormality of the Huntington disease gene. Genetic technology has the potential to identify individuals at risk for these conditions at any age prior to the onset of symptoms. In the case of a woman with a strong family history of breast cancer, it may be appropriate to screen that woman by genetic testing to determine her genetic risk to develop breast cancer. Screening would allow for early detection or prevention of breast cancer in a woman with the mutation in BRCA1 or BRCA2. In the case of Huntington disease, an autosomal dominant condition, children of an affected individual are at 50% risk for developing the condition in adulthood, but there exist no medical strategies for treatment or cure. Genetic testing is appropriate for medical information and for personal decision-making on lifestyle changes in the case of individuals at risk for Huntington disease. A third scenario is the testing of children (<18 years) for medical conditions that may present in adulthood; like the susceptibility to breast cancer or Huntington disease. In the genetic community it is considered unethical to test children for adult onset disorders prior to their age of consent. This applies to children born into families who are at increased risk for an adult onset disease, or children being placed for adoption with no prior risk factors.

The incidence of discriminatory actions based upon genetic information

Findings

1. The committee is aware of the possibility of discrimination for this category of genetic testing, but finds no obvious discrimination documented within the state of Washington based on information obtained by genetic testing on the predictive identification of late-onset disorders.

Conclusions

1. It is this category of the use of genetic information, however, that may place individuals at risk for genetic discrimination should such information exceed the bounds of the medical care system. For example, a woman identified in a family with an abnormality of a BRCA1 gene could theoretically be discriminated against in obtaining health insurance or employment because of the perceived increased fiduciary risk she would present to an employer or in social stigmatization. Similarly, an individual identified at age 20 as carrying the gene for Huntington disease could be discriminated against in employment, obtaining health insurance, or from individual or group life insurance.

Strategies to safeguard civil rights and privacy related to genetic information

Recommendations

1. The reports of genetic testing should remain in the medical records and have the same protection as other sensitive medical information. Such information is protected by hospital policy, Washington state statute, and HIPAA regulations.

Remedies to compensate individuals for inappropriate use of genetic information

Findings

1. The inappropriate use of private genetic information for predictive diseases would fall under the recommendations from another portion of the Genetic Task Force Report.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

Findings

1. The committee finds that incentives for research and development on the use of genetic testing to promote predictive testing of late-onset diseases is an active research endeavor within the medical community.
2. There is research and funding available for predicting individuals at risk for developing diabetes, hypertension, renal disease, and cardiovascular disorders for which intervention strategies may be available.

Conclusions

1. The committee concludes that development of testing for risk factors associated with these common diseases will have a beneficial effect on public health policy and the welfare and safety of the population. The research should be encouraged as a means of improving the health of the population.

Additional Findings, Conclusions and Recommendations

Findings

1. In view of the expanding use of genetic testing for the detection of genetic disorders and the prediction of future disease, there is a need for genetic counseling to assist physicians and individuals with selection of tests and interpretation of results. The State of Washington has no academic program to train genetic counselors.

Recommendations

1. It is recommended that serious attention be given to establishing a graduate program in genetic counseling at the University of Washington to address the current and future needs of the state's population.

Genetics Task Force Subcommittee Two Report

Subcommittee Title: State Mandated DNA Collection/Genetic Testing
Subcommittee Chair: Maxine Hayes
Subcommittee Members: Phil Bereano, Howard Coleman, Suzanne Plemmons, and Brenda Suiter
Date of Report: July 1, 2002

Part I Newborn Screening

Background
State law (Chapter 70.83 RCW) requires: "… screening tests of all newborn infants before they are discharged from the hospital for the detection of phenylketonuria and other heritable or metabolic disorders leading to mental retardation or physical defects as defined by the state board of health: Provided That no such tests shall be given to any newborn infant whose parents or guardian object thereto on the grounds that such tests conflict with their religious tenets and practices." Board of Health regulations (Chapter 246-650 WAC) adopted pursuant to the statute direct hospitals to obtain blood specimens from infants and send them to the State Public Health Laboratory for testing. The specimens consist of a few drops of blood that are absorbed onto a filter paper form. The blood is allowed to dry before shipping.

The incidence of discriminatory actions based upon genetic information

Findings
1. Over one and one half million infants have been tested by Washington's program since it was centralized in 1977. In the United States, nearly four million infants are screened each year in similar programs.
2. No incidents of discrimination related to the dried blood spot specimens are known to program staff. However, there is no active system of surveillance, and this observation does not rule out the possibility that there may have been misuses of the collected data.

Conclusions
1. There is no evidence of discrimination under the newborn screening program in Washington State.

Recommendations
1. None.

Strategies to safeguard civil rights and privacy related to genetic information

Findings
1. These specimens and the testing results are considered "health care information" under the State Uniform Health Care Information Act, Chapter 70.02 RCW; and as "personal records" under Release of Records for Research, Chapter 42-48 RCW.

Conclusions

1. The subcommittee felt that the protections in place for the newborn screening system appear to be adequate to protect civil rights and privacy.

Recommendations
1. None

Remedies to compensate individuals for inappropriate use of genetic information

Findings
1. The Uniform Health Care Information Act provides that action can be brought against a "…health care provider or facility who has not complied with this chapter." Relief is limited to actual damages and attorney fees and other expenses of bringing the action. Relief must be sought within two years after the cause of action is discovered.
2. The Use of Records for Research statute provides that any unauthorized disclosure by a researcher of individually identifiable personal information obtained from a state agency is a gross misdemeanor and that any violation of the statute may subject the researcher or state agency to a civil penalty of not more than ten thousand dollars for each violation.

Conclusions
1. Both the Uniform Health Care Information Act and Use of Records for Research statute provide remedies for inappropriate use.

Recommendations
1. None.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

Findings
1. Newborn Screening program policy allows use of the specimens for research with appropriate safeguards.

Conclusions
1. The subcommittee judged that protections provided by Department of Health policy, DSHS/DOH Human Subject Research Review Board policy, and Chapter 42.48 RCW, Release of Records for Research appear to be adequate to protect individuals without unnecessarily impeding research to promote public health safety and welfare.

Recommendations
1. None

Part II Mandatory DNA Collection for Forensic Purposes

Background
Recently amended state law, DNA Data Base, Chapter 43.43 RCW, requires that: "Every adult or juvenile individual convicted of a felony, stalking … harassment … or communicating with a minor for immoral purposes … must have a biological sample collected for purposes of DNA

identification analysis …" The samples are to be tested and may be retained by the Forensic Services Bureau of the Washington State Patrol. The statute restricts uses to "… identification analysis and prosecution of a criminal offense or for the identification of human remains or missing persons" or "… improving the operation of the *[DNA identification]* system." The statute allows the Patrol to submit DNA test results to the Federal Bureau of Investigation (FBI) combined DNA index system (CODIS) which is authorized under the DNA Identification Act of 1994(42 U.S.C.A§14132).

The incidence of discriminatory actions based upon genetic information

Findings
1. No information was found related to possible discriminatory actions. However, there is no active system of surveillance, and this observation does not rule out the possibility that there may have been misuses of the collected data.
2. The sections of DNA that are analyzed have been carefully selected to avoid regions related to any medical condition or disease.

Conclusions
1. No incidents of discriminatory actions were identified.

Recommendations
1. None

Strategies to safeguard civil rights and privacy related to genetic information

Findings
1. Uses are specifically restricted in both state and federal law
2. The tests do not reveal information relating to medical conditions or disease.

Conclusions
1. The majority of the Subcommittee concluded that protections appear to be adequate.
2. A minority advocated for destroying the specimens after they are tested and the DNA code has been entered in the database. A Minority Opinion will be submitted with the final report.

Recommendations
1. None

Remedies to compensate individuals for inappropriate use of genetic information

Findings
1. The state law does not provide specific remedies beyond the existing tort system.
2. The federal DNA Identification Act of 1994 establishes criminal penalties for individuals who knowingly violate privacy protection standards and provides that access to the system is subject to cancellation if privacy requirements are not met. There are no specific remedies for individuals for inappropriate use.

Conclusions

1. Federal law provides penalties for inappropriate use, neither federal nor state law provide specific remedies to individuals, beyond the existing tort system.

Recommendations

1. None

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

Findings

1. State law does not allow use of the samples or test results for research beyond that which may "… improve the operation of the system…"
2. The federal law allows use of the test information if personally identifiable information is removed, for "… a population statistics database, for identification research and protocol development purposes, or for quality control purposes."

Conclusions

1. The subcommittee observed that, given the limited nature of the data provided by testing, further incentives are not warranted.

Recommendations

1. None

Part III Summary

The subcommittee found that safeguards for these two specific mandated systems appear to be adequate to protect civil liberties and privacy. However, it could identify no circumstances that would justify the creation of any additional mandatory DNA/genetic testing systems. Members caution that any infringement on an individual's rights to free choice regarding their DNA/genetic information is perilous and to be avoided in all but the most specific and compelling circumstances found in these two systems.

Finally, the subcommittee recommends that the Task Force at large consider *A Proposed Model Law to Prevent Genetic Discrimination* which was developed by the Council for Responsible Genetics, a non-profit/non-governmental organization devoted to fostering public debate about the social, ethical, and environmental implications of the new genetic technologies. This model law was developed specifically to help address issues that the Task Force has been charged to review. See the attached document for the text of this law.

Genetics Task Force Subcommittee Three Report

Subcommittee Title: Subcommittee 3 – The Use of Genetic Information in Research
Subcommittee Chair: Peter Byers, M.D.
Subcommittee Members: Helen McGough, Phillip Bereano, JD**,** Amanda DuBois, JD, Vicki Hohner
Date of Report: July 31, 2002

The incidence of discriminatory actions based upon genetic information

Findings

1. The Washington State Human Rights Commission (WSHRC) has received no reports of discriminatory actions based on the results of genetic studies from research activities occurring in Washington.
2. The University of Washington IRB has received no complaints of such behavior as a consequence of research performed under its aegis.
3. The Washington State Human Rights Commission (WSHRC) has the authority to investigate claims of discrimination based on genetic information and to punish violators if evidence supports the claim (RCW 49.60). Lawsuits may also be filed under the ADA if genetic discrimination occurs. Criminal and civil penalties may be assessed if violations are proven. The scope of this protection is unclear.
4. When research data are considered as part of "medical information" they derive all aspects of protection afforded those data from State and Federal laws and regulations.
5. There is a formal reporting system for perceived abuses that occur to a subject in the course of subject participation in research covered by federal regulations (45 CFR 46). This pathway is by the subject and through the principal investigator and/or the Investigational Review Board (IRB) that evaluated the proposal for human subjects research, or directly to the Federal oversight agency e.g., Office of Human Research Protection (OHRP) or the US Food and Drug Administration.
6. There is no required reporting system for un-regulated research.

Conclusions

Based on evidence received we conclude that:

1. RCW 49.60 and RCW 70.02 substantive legal protection against discrimination based on use of genetic information (regardless of the source)
2. Gaps in protection exist that may leave research subjects vulnerable to the misuse of genetic information obtained in research, if that information would have to be reported by the subject to insurers, employers, or others who may make decisions on the basis of that information and use it in an adverse fashion for the individual.
3. Predictive test results in the absence of a current diagnosis made by clinical examination, whether derived as part of clinical testing or from research studies, cannot be requested or used by an insurer in making a decision about insurability WAC 284.43.720).
4. No existing legislation addresses the type of genetic information an insurance company or employer may request and expect to receive from an individual or limits subsequent

disclosure, unless this information is considered as "medical information" in the context of RCW 49.60 and RCW 70.02.

5. There are no external mechanisms to monitor compliance with the ADA or RCW 49.60, which leaves the responsibility to report violations to subject or witnesses who feel genetic information may have been used in an adverse fashion.

Recommendations

We recommend that:

1. The Legislature authorize the funding of efforts by the Department of Health to educate consumers, research subjects, researchers, health care providers, employers, and insurers about how genetic information derived from DNA sequences, as part of medical information, can be used, the concepts and consequences of anonymity in research, and on the reporting and other mechanisms available to those who believe they have been discriminated against.

<u>Strategies to safeguard civil rights and privacy related to genetic information</u>

Findings

1. Several layers of legislation exist to safeguard civil rights and privacy related to genetic information used for or generated by research including federal HIPAA regulations, the Washington State Uniform Health Care Information Act (RCW 70.02), 45 CFR 46 and 21 CFR 50/56. Researchers may also apply for a federal certificate of confidentiality that protects them from court-ordered disclosure of research data under most circumstances. No direct enforcement mechanism is in place for HIPAA or RCW 70.02. As a result, regulatory agencies must rely on reports of violations rather than inspections. Institutional Review Boards (IRBs) and research projects regulated by the U.S. Food and Drug Administration (FDA) under 21 CFR 50/56 are subject to routine inspections for compliance and have extensive reporting responsibilities to parent agencies.
2. Genetic research activities conducted without federal financial support, in facilities that have not voluntarily adopted the federal protections, and that do not involve FDA-regulated test articles are not required to conform to and follow legal requirements and standards established for the involvement of human subjects in research.
3. According to federal law, different research study designs require different levels of informed consent. For example, research using biological samples from which all information that could identify the individual from whom they were obtained has been removed ("anonymized" samples) may not require informed consent of the individuals from whom they were obtained. However, research using samples that maintain information from which the donor can be identified almost always requires the consent of the individual who originally provided the information or biological sample.

Conclusions

Based on information provided we conclude that:

1. The majority of the members of this committee thought that existing federal and state legislation provide substantial protection with respect to the privacy and civil rights of research subjects

2. Knowledge of existing laws that protect privacy and civil rights may encourage people to participate in genetic research.
3. Waivers of consent for research on previously obtained tissues or samples are appropriate for some types of research under current Federal regulations.
4. Appropriate monitoring/oversight systems are lacking for research on human subjects in some settings.

Recommendations

We recommend that:

1. Research involving human subjects in the State of Washington be subject to the standards that are in place for federally funded human subjects research
2. Researchers, subjects, health care providers, insurers, and employers have access to all existing laws that protect the privacy of medical information, including DNA-based information.
3. State policies leave the responsibility of monitoring research activities that involve human subjects to IRBs
4. A minority of the committee members recommended that the Legislature of the State of Washington propose and enact legislation (either as new legislation or as amendments to existing statutes) that explicitly defines genetic discrimination, genetic information, and privacy rights of individuals with respect to genetic information.

<u>Remedies to compensate individuals for inappropriate use of genetic information</u>

Findings

1. Existing laws such as HIPAA, ADA, RCW 70.02, and RCW 49.60 contain provisions for criminal and/or civil penalties in the case of violations including privacy violations and discrimination.
2. Researchers and institutions housing researchers found to be in violation of federal regulations are subject to fines, suspension of research activities or loss of federal funding. They may also be sued by individuals who claim wrongdoing.

Conclusions

We conclude that:

1. The majority of the committee concluded that existing penalties for the violation of laws protecting the privacy and civil rights of individuals who provide genetic information for research purposes are adequate.
2. A minority concluded that these laws were inadequate.

Recommendations

We recommend:

1. The majority of the committee recommended that no further action be taken by the state**.**
2. A minority of the committee recommended that, as has been done in many other states, Washington pass legislation that protects the privacy of genetic information, defines and outlaws genetic discrimination and provides avenues for redress whether violations are proven.

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

Findings

1. Genetic research will contribute to the development of understanding of many aspects of human biology. and tools for medical care including diagnosis, disease prevention, and treatment.
2. Currently many genetic tests exist, but the knowledge needed to apply many of them in a clinical setting–eg, significance of outcomes, consequences, etc-- is lacking.
3. Development of genetic tests/technologies and some pharmaceuticals requires access to DNA samples.
4. Anonymous samples are not always adequate for research purposes. For example, identifiers are needed to match clinical data with genotype data.
5. Genetic research aimed at associating genotypes with phenotypic profiles may be important to advance medical and public health knowledge including screening programs, education/intervention programs, and therapies.

Conclusions

We conclude that:

1. The development of genetic tests far outpaces the availability of information and personnel to interpret and apply the test results in a health care setting. In the current health care environment the costs for making genetic testing available, as a result of research and development studies, may impede equitable availability of such resources to all segments of our population.
2. Research studies that use identifiable DNA samples or anonymous DNA samples are among types of biomedical research important for the advancement of medical and public health knowledge and may provide benefits to the citizens of Washington.
3. Academic and private researchers receive adequate incentives to conduct genetic research.

Recommendations

We recommend that:

1. In all research that involves genetic information from individuals explicit voluntary consent or assent should be obtained, as detailed in current applicable law and regulations.

Genetics Task Force Subcommittee Four Report

Subcommittee Title: The Use of Genetic Information for Other Social Purposes
Subcommittee Chair: Mellani Hughes
Subcommittee Members: Wylie Burke, Joe Finkbonner, Ty Thorsen, Nancy Fisher
Date of Report: July 31, 2002

The incidence of discriminatory actions based upon genetic information

Findings

1. The Task Force received little information on the incidence of discrimination based on genetic information in the State of Washington. Information provided by the Department of Health Genetic Services Section includes three cases in which family history or genetic status may have been used to adversely discriminate against an individual over the course of the last 10 years. The rest of the complaints were based on the need for additional education and/or resources.
2. The Washington State Human Rights Commission reported that no claims of discrimination based on genetic information have been received by the WSHRC.
3. Statistical tables used by life insurance companies inherently contain genetic information, as a variety of factors could be construed as 'genetic' and this is highly dependent on the definition of genetic information. For example, family history is a common and allowable question for insurance coverage but could potentially be included in a definition of genetic information.
4. Agencies do not systematically survey people or make proactive efforts to collect information regarding discrimination based on genetic information, but agencies such as DOH, OIC, and WSHRC have reporting systems in place for receiving complaints.
5. Health, life, and disability insurers view genetic information as a category of health care/medical information.
6. State laws and industry practice disallow the use of health information (including genetic information) to set rates for, cancel or non-renew a consumer of health insurance. Disability and life insurance may use health information to underwrite a policy but state law and/or industry practice prohibits the use of health information to cancel or non-renew a current consumer of these types of policies.
7. WSHRC interprets existing state and federal laws to be applicable in cases of employment or other discrimination based on genetic information, however this has not been challenged in the courts.
8. A minority of the subcommittee members is concerned that the protection provided by the Americans with Disabilities Act (ADA) against discrimination based on genetic information may be limited, particularly in light of recent Supreme Court rulings limiting the scope of protection provided by ADA.

Conclusions

1. Evidence of discrimination based on genetic information received by the task force does not suggest widespread problems regarding the use of genetic information for social

purposes such as health, life, or disability insurance, or employment. However, the incidents reported to the DOH GSS may not represent all such events. Currently, quantitative data on the extent of actual or perceived discrimination based on genetic information may be lacking.

2. Existing regulatory policies and practices provide some protections against discrimination based on genetic information; in particular, state and federal laws protecting the privacy of health information and limiting the use of health information by employers and insurers provide important protections. However, one committee member believes that gaps exist in the protection provided by these existing laws. Examples of existing laws include the following:
    a. The Washington Law Against Discrimination (RCW 49.60 et seq. and WAC 162-22 et seq.) prohibits discriminating against an individual based on genetic information in employment, real estate, public accommodation, credit, and insurance. RCW 49.44.010 also prohibits "blacklisting" by employers.
    b. The Federal Americans with Disabilities Act has been interpreted by the EEOC as prohibiting discrimination based on genetics. See II.A.1. below.
    c. Jon Hedegard of the OIC stated that, as applied to group and individual insurance, Washington State laws do not offer direct prohibition against the use of genetic information, but those laws are written in such a way that it is not possible. See, e.g., RCW 48.43 et seq.
    d. RCW 48.18.480 prohibits unfair discrimination in insurance matters, and the OIC has heard of no problems in this area.
3. One subcommittee member recommends changing RCW 49.60, the Law Against Discrimination, to explicitly include "genetic information" in the list of characteristics that receive protection under the law. As it is written, the law only explicitly protects discrimination based on "sex, race, creed, color, national origin, marital status, age or the presence of any sensory, mental or physical disability, or the use of a trained dog guide or service animal by a disabled person. In addition, a minority recommend that the Uniform Health Information Act be amended to define genetic information obtained as a result of participation in human subjects research be defined as medical information. The remaining subcommittee members believe that no additional safeguards are needed in either area of the law.

Recommendations

1. The subcommittee did not identify any areas in which additional legislation was deemed necessary for the protection of individuals against discrimination based on the use of genetic information in insurance or employment settings.

<u>Strategies to safeguard civil rights and privacy related to genetic information</u>

Findings

1. Findings A minority of the subcommittee members believed that Washington State's consanguinity laws regarding marriage may be a violation of privacy rights and should be reviewed. RCW 26.04.020 lists conditions under which marriage is prohibited in this state. RCW 26.04.020(1)(b) specifically prohibits marriage "when the husband and wife are nearer of kin to each other than second cousins…" However, current data indicate

that the genetic risk for progeny of first cousin marriages is only minimally increased above population risk. "Genetic counseling and screening of consanguineous couples and their offspring: recommendations of the National Society of Genetic Counselors." Journal of Genetic Counseling 11(2) April 2002, 97-119.

2. The ADA and EEOC rules define the type of information an employer can request and use in making employment decisions. The ADA states that before making an offer of employment, an employer may not ask job applicants about the existence, nature, or severity of a disability. Applicants may be asked about their ability to perform job functions. A job offer may be conditioned on the results of a medical examination, but only if the examination is required for all entering employees in the same job category. Medical examinations of existing employees must be job-related and consistent with business necessity. The Equal Employment Opportunities Commission (EEOC) writes rules pertaining to, and oversees the implementation of, the ADA. The EEOC rules address the retention, storage, and use of employee's health information. The EEOC interprets the scope of the ADA to include genetic tests and genetic information. The EEOC considers that employers who discriminate against employees on the basis of predictive genetic tests "regard" the employees as having a disabling impairment and are therefore acting in violation of the ADA (2EEOC Compliance Manual, secs. 902-45, March 14, 1995).

3. Both state and federal law protects the privacy of medical records. The following list provides examples of such laws:
   a. The federal act, HIPAA, provides individuals in the large group health insurance market with new national privacy rights, which are broadly enough defined to include genetic information. There is a specific provision that precludes the use of genetic information for insurance purposes. Less restrictive state laws are preempted. HIPAA does not provide protection for the individual or small group health insurance market.
   b. The Washington Uniform Health Care Act of 1991 (RCW 70.02 et seq.) covers identifiable health care information in any form and applies to health care providers and insurers. DNA was added to the definition of "health care information" by ESSB 5207, which was passed by the Legislature in March 2002.
   c. The Washington Uniform Health Information Act is based on the model law from which the federal law, HIPAA, was promulgated and provides similar protections.
   d. The Washington State Patients' Bill of Rights also provides privacy protections and is applicable to insurers and third party payors.
   e. WAC 284-04 et seq. also provides protections similar to those in HIPAA.
   f. The Governor's Executive Order on Privacy 2000 addresses privacy concerns in regard to state government agencies and contractors.
   g. Case law may also arguably prohibit the divulgence of genetic information, at least in certain circumstances, based on a 1997 case against Group Health Cooperative for using an employee's mental health records in a training session for administrative employees.
   h. RCW 49.44.010 prohibits "blacklisting" by employers.
   i. Joan Mell, an attorney and legislative consultant who testified before the task force, stated that state law reflects consistent protection of privacy of body and bodily functions.

Conclusions

1. Existing laws and regulations are sufficient to protect the privacy of individuals in regard to genetic information that is included in the medical record or obtained as a part of health care.
2. Existing state and federal laws as well as industry practices/policies provide protection for an individual's privacy and civil liberties with respect to health, life, and disability insurance.
3. Existing laws provide protection against employment discrimination or other privacy/civil rights violations.
4. The Washington State law prohibiting marriage of first cousins may not be justified on a scientific basis.

Recommendations

1. The subcommittee did not identify any areas of law in which additional legislation is needed to protect the privacy of individuals with regard to the use/disclosure of genetic information.
2. A minority of the subcommittee members recommended revising the Uniform Health Information Act to ensure that genetic information obtained in the course of research participation is included in the definition of medical information.
3. One subcommittee member recommended changing RCW 49.60, the Law Against Discrimination, to explicitly include "genetic information" in the list of characteristics that receive protection under this law.
4. A minority of the subcommittee recommended that repeal of the Washington State law prohibiting marriage of first cousins should be considered.

<u>Remedies to compensate individuals for inappropriate use of genetic information</u>

Findings

1. Federal and state laws provide for civil and/or criminal penalties for violations of privacy and/or anti-discrimination laws.

Conclusions

1. The existing tort system contains an avenue to compensate individuals for inappropriate use of genetic information.

Recommendations

1. The Task Force did not identify any additional action required by the State.

<u>Incentives for further research and development on the use of DNA to promote public health, safety and welfare</u>

Findings

1. Biotechnology and research endeavors in Washington are sensitive to changes in legislation that may affect their ability to conduct research.
2. The Task Force heard from several presenters that fear of discrimination is a reason that people do not participate in genetic studies.

3. Research involving human subjects may be subject to different oversight requirements depending on the source of funding/regulation or level of anonymity involved in the data collection process.

Conclusions

1. Washington law must be such that biotechnology companies and other researchers want to locate or continue to remain and operate within the state.
2. Policies are needed to address the perception of the risk of discrimination associated with participating in a genetic research study.

Recommendations

1. The State implement programs or other processes to educate the public, researchers, employers, and health care providers about existing measures to protect an individual's civil liberties and right to privacy. Such a program may reduce the perception that the risk of discrimination is high and encourage people to participate in genetic research.
2. Any process to create policies to address the use of genetic information in research should invite participation from all stakeholders.

Appendix F

Newborn Screening and Privacy:
A Summary of Relevant Laws, Regulations and Policies in Washington State

Introduction

Policymakers are giving considerable attention to the issue of appropriate use and protection of genetic information at both the state and federal levels. Much of this attention is focused on state mandated newborn screening programs. Administrators of these programs are considering how they can best ensure that the blood samples they collect from infants at birth and often store for many years are kept private and are not misused. Simultaneously, researchers are seeking increased access to this important source of data for public health and genetic research. Policy around the privacy of newborn screening specimens must balance these two important interests.

Several different laws, regulations, and policies in Washington State address issues of privacy and research. However, existing legislation does not exclusively address these issues in relation to the newborn screening (NBS) specimens collected by the Washington State Department of Health (DOH). In particular, no existing law has been tested in court. Therefore, the DOH drafted policies that specifically apply to this unique source of information in an attempt to address the gap in existing legislation in the state. The following provides a brief overview of the NBS Specimen Policy Draft.

Newborn Screening Program Specimen Policy DRAFT (January 29, 2002)

The DOH drafted internal policy to address privacy issues that arise as a result of collecting and storing blood spots from all newborn babies in the State of Washington. The policy rationale holds that a specific privacy policy for newborn screening (NBS) specimens, as separate from other healthcare information, is required because of certain unique characteristics of the dried blood spot. The unique characteristics of dried spots include their stability; the presence of DNA in the blood spots; the fact that identifying information is not easily separated from the blood spots; and fact that the state mandates the collection of the blood spots. Specifically with relation to genetic research, DNA is a highly stable molecule, and therefore will be preserved for the life of the blood spot.

The NBS Specimen Policy draft document identifies five policy areas around the privacy of newborn screening samples: ownership, retention/destruction, access, release, and notification.

Ownership of one's own genetic material is becoming an increasingly contentious policy issue, especially with relation to commercial interests and control over release to third parties. The DOH has determined, based on interpretations of RCW 40.12.010 and 70.02, that the blood spot and related information is in fact the property of the State of Washington. This places responsibility for the appropriate stewardship of the samples with the DOH.

Storage, as it regulates physical access to samples, is potentially of great concern to both the DOH and the individual's from whom the samples were obtained. Specifically, the NBS Specimen Policy states that the specimens shall be kept at ambient room temperature in secured storage facilities to prevent access by unauthorized individuals. This is in accordance with RCW 70.02.140, Security Safeguards, which

states, “a health care provider shall effect reasonable safeguards for the security of all health care information it maintains.” In this case, the DOH can be considered a health care provider.

In addition to security measures, the DOH policy outlines clear guidelines for the retention and destruction of the blood spots. After 21 years, the information form and blood spot will be destroyed by incineration. Few states require the retention of the blood spot for 21 years, but Washington’s policy is consistent with RCW 70.41.190, which requires hospitals to retain samples for at least three years after attainment of the age of eighteen. A parent or legal guardian, or patient age 18 or older, can request the destruction of the residual newborn screening blood spot specimens, at any time after all required screening tests have been performed and the patient’s screening/clinical status related to such tests has been resolved.

The policy restricts access to the samples to DOH employees and those contractors or others approved by the Director of Newborn Screening. In order to gain access, the individual must be in compliance with all state and federal laws that safeguard the privacy and confidentiality of medical information. In Washington, these include 45CFR46; RCW 70.02; RCW 42.48; and WAC 388-10, the Protection of Human Research Subjects

Release of the samples or information to third parties could potentially impinge on the privacy rights of individuals. Therefore, an individually identifiable specimen can only be released to: a health care provider at the request of the patient in the form of written informed consent signed by the patient or legal representative; a researcher who obtained the patient’s written informed consent and DOH/DSHS Review Board approval; or a named person in a legally executed subpoena. Importantly, in an attempt to facilitate genetic and public health research, anonymous samples may be released if: the investigation design is adequate to ensure anonymity; all tests are completed and the status of the infant is resolved; one useful spot will remain; resources exist for spot extraction; and the investigation has met with DOH/DSHS Review Board approval. However, DOH will not release a specimen directly to a parent.

The NBS Specimen Policy also outlines steps to notify parents of their privacy rights in relation to state mandated newborn screening. This includes a pamphlet titled “Newborn Screening and Your Baby”, which is intended to educate parents about the storage, access and retention policies of the DOH, as well as their rights under RCW 70.02. This process complies with 70.02.120, Notice of Information Practices, which requires health care providers to conspicuously display their information practices to the patient.

<u>Other Relevant Law: RCW 70.02 and RCW 42.48</u>

RCW 70.02, the Uniform Health Care Information Act, establishes a law governing the use and disclosure of health care information. NBS specimens are interpreted to fall within the definition of “health care information” as defined in RCW 70.02.010: “any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care, including a patient's deoxyribonucleic acid and identified sequence of chemical base pairs.” Pursuant to the definition of health care information, RCW 70.02.020 stipulates that a “health care provider” (in the case of NBS, DOH is a

health care provider) may not disclose health care information about a patient to any other person without the patient's written authorization. Importantly, and in accordance with the Guide to DSHS/DOH Policy on Protection of Human Research Subjects, RCW 70.02.050 stipulates that health care information may be released without authorization for research purposes if an IRB has determined that the project is sufficiently important to justify the violation of the patient's privacy; the project is impractical without release of individually-identified data; the project safeguards the information adequately; and the project provides for the destruction of the individually identifiable records at the earliest date possible.

RCW 42.48, Release of Records for Research, aims to regulate the release of individually identifiable records for research purposes. NBS blood spots and related forms are interpreted to fall within the definition of "records". The definition of "personal record" pursuant to 42.48.020 is any information obtained or maintained by a state agency which refers to a person and which is declared exempt from public disclosure, confidential or privileged under state or federal law. This law states that a "state agency may authorize or provide access to or provide copies of an individually identifiable personal record for *research purposes* if informed written consent for the disclosure has been given". According to the Guide to DSHS/DOH Policy on Protection of Human Research Subjects, such research will be subject to approval by the DOH/DSHS Human Subjects Review Board. This law does not address requirements around the release of anonymous samples for research purposes; it only addresses the release of individually identifiable samples. The Guide to DSHS/DOH Policy on Protection of Human Research Subjects addresses the release of anonymous samples or information by stating that research using information that is disclosed to researchers in such a manner that it is not identifiable, is exempt from review by the DSHS/DOH Human Research Review Board.

Individually identifiable records may also be released without informed consent in certain instances according to the Policy Guide. Such information may be released without garnering informed consent if the State establishes a human research review board (which DOH/DSHS has) and this review board finds that: 1) the research cannot be conducted without the disclosure of the information and waiver of informed consent, 2) risks have been minimized, 3) resulting benefits are expected to outweigh remaining risks, 4) it does not violate federal law or regulations, and 5) a legally binding confidentiality agreement has been entered.

Resources

DSHS and DOH. July 1, 1998. Guide to DSHS/DOH Policy on Protection of Human Research Subjects.

RCW 42.48 Release of Records for Research.

DOH. January 29, 2002. NBS Specimen Policy DRAFT.

RCW 70.02 Uniform Health Care Information Act.

NBS Specimen Policy DRAFT

January 29, 2002

Purpose: Development of a comprehensive policy for storage, access, and release of newborn screening dried blood spot specimen/information forms.

Background

The newborn screening dried blood specimen is somewhat unique among specimens typically dealt with by the Department of Health's Public Health Laboratories:

- The dried blood spots are relatively stable and capable of being stored for long periods with no special processing.
- The dried blood spots and specimen information are contained on a single form and are not easily separated.
- The pattern of "punches" taken from the dried blood spots provides indirect information about the testing performed on them.
- DNA contained in the dried blood can provide information to positively link the specimen to a specific child (in the event of uncertainty regarding accuracy of identifying information).

Definitions:

The Public Health Laboratories is a "Health care facility" as defined by the Uniform Healthcare Information Act, RCW 70.02.010(5): "…a hospital, clinic, nursing home, laboratory, office or similar place where a health car provider provides health care to patients".

The Office of Newborn Screening is a "Health care provider" as defined by the Uniform Healthcare Information Act, RCW 70.02.010(7): "…a person who is …authorized by the law of this state to provide health care in the ordinary course of business…"

The Office of Newborn Screening is also a "Person" as defined by the Uniform Healthcare Information Act, RCW 70.02.010(11): "…an individual, corporation…government, governmental subdivision or agency, or any other legal or commercial entity."

Newborn Screening is "Health care" as defined by the Uniform Healthcare Information Act, RCW 70.02.010(4): "…any care, service, or procedure provided by a health care provider: (a) to diagnose, treat, or maintain a patient's physical or mental condition;"

The newborn screening specimen/information form (including dried blood specimen) is "Health care information" as defined by the Uniform Healthcare Information Act, RCW 70.02.010(6): "…any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and directly relates to the patient's health care, including a patient's deoxyribonucleic acid..."

Policies

1. **Ownership: The specimen and information form is the property of the State of Washington**.

   Rationale: RCW 40.14.020 states: "All public records shall be and remain the property of the state of Washington." The information portion of the form is clearly a "public record" as defined in Section 010 of that statute. It is less clear, however, whether the definition includes the dried blood specimen portion since the central concept is that of a "…document, regardless of physical form or characteristics…" Nonetheless, it seems reasonable to extend the concept of public record to "health care information"(as defined in 70.02.010) that is collected by a public entity such as the Newborn Screening Program. As such, the "public record" includes the dried blood specimen.

   Also, the concept of ownership of health care information by the health care facility that possesses it is consistent with the other provisions of Chapter 70.02 RCW.

   Finally, Assistant Attorney General Richard McCartan concluded in a memo to Michael Glass dated May 22, 2001 that the dried blood specimen is not a public record covered in the public disclosure law, Chapter 42.17 RCW. In follow-up correspondence on May 25, 2001 he offered "My opinion is that the specimens "belong" to the Department…" (of Health).

2. **Storage: The specimen/information forms shall be kept at ambient temperature in secured storage to preserve their confidentiality and prevent access by unauthorized persons.**

   Rationale: RCW 70.02.150: Security Safeguards; requires that "A health care provider shall effect reasonable safeguards for the security of all health care information it maintains".

   Many of the chemical components of the specimen are more stable at refrigerated temperatures, however, preservation of chemical integrity is not necessary for the primary purpose of storage. A possible exception could be the use of DNA to validate specimen identification, however, since DNA remains stable under a wide range of storage conditions the additional cost of refrigerated storage is not warranted.

3. **Retention/destruction: The specimen/information forms shall be retained until the child is 21 years old. Since specimens are collected during the first weeks of life, this will be achieved by retaining the forms for 21 years. After this time the form will be destroyed by incineration.**

Rationale: Washington's Medical Test Site Rules (WAC 246-338-070) specify minimum retention times for laboratory records of, from 2 years for most specialties, to ten years for cytology reports, histopathology reports and and stained slides. The longer retention for newborn screening records is consistent with requirements for hospitals (RCW 70.41.190) which must "…retain and preserve all medical records which relate directly to the care and treatment…of minors…for a period of no less than three years following the attainment of the age of eighteen years…" (emphasis added) The same requirements are applied to hospice (WAC 246-331-165) and home health care (WAC-327-165).

This is also consistent with published recommendations regarding legal liability for newborn screening programs: "… lawsuits could generally be brought until the infant is 21 years of age…Records should be maintained until the last possibility that an individual may bring a lawsuit based on that screening." (Andrews, JD, editor. Legal liability and quality assurance in newborn screening, p55, American Bar Foundation, Chicago IL, 1985).

Incineration is the only reliable, cost effective method to assure the complete destruction of the dried blood specimen.

4. **Access: Access to stored specimen/information forms shall be restricted to Department of Health employees and those contractors or others approved by the Director of Newborn Screening as necessary to meet specific program needs. Access is contingent upon compliance with all applicable state laws, regulations, and policies safeguarding the privacy and confidentiality of medical information. The Director shall assure that those granted access understand confidentiality requirements and have a signed confidentiality agreement on file.**

Rationale: Consistent with agency and division policy, this provision provides physical security while allowing access necessary to meet legitimate agency and program needs. It further provides that those with access understand and follow confidentiality/privacy restrictions.

5. **Release: Dried blood spot samples and specimen information will only be released according to the following:**

A sample from a specimen and copies of associated information (demographics and testing results, if requested) will be released to:

- A health care provider at the request of the patient or their legal representative after completing and signing the form "Release of Information: Newborn Screening Specimen".
- A researcher with the written, informed consent of the patient or their legal representative as part of a research project that has been reviewed and

approved by the DOH/DSHS Human Subjects Review Board and the Secretary or designee of the Department of Health.
- A named person in a legally executed subpoena following review and approval of the State Attorney General.

Anonymous samples may be released when the intended use has significant potential health benefit and each of the following criteria have been met:

- The investigation design is adequate to assure anonymity will be preserved.
- All newborn screening tests have been completed and the status of the infant is resolved.
- At least one fully adequate spot will remain after the anonymous sample has been taken.
- Sufficient resources (personnel) are available for extracting the samples.
- The DOH/DSHS Human Subjects Research Review Board has reviewed and approved the investigation. This requirement may be waved by the Director of Newborn Screening for a very small (i.e.: less than 100 sample) pilot study where the intent is to evaluate a testing tool, as opposed to an evaluation where the intent is to measure some characteristic of a population).

Dried blood samples and specimen information will not be released directly to a patient, their parent or legal representative except as described above.

Rationale: This has been designed to be consistent with State laws, regulations and policies, notably the requirements of the Chapter 70.02 RCW, the Uniform Health Care Information Act and Chapter 42.48 RCW, Release of Records for Research. It is intended to prevent violation of any person's privacy or confidentiality of their private information while allowing appropriate medical, legal, and research uses.

The restriction against releasing specimens directly to parents is consistent with our established procedures of working through the patient's health care providers regarding screening outcomes WAC 246-650-020(2): "…the department shall…(b) report significant screening test results to the infant's attending physician…and (c) offer …resources of the department to physicians attending infants…" and in part by RCW 70.02.090(3) which stipulates that a provider who denies a patient's request to examine or copy medical information shall allow examination and copying by another health care provider selected by the patient.

Richard McCartan, Assistant Attorney General reviewed these requirements and his May 22, 2001 memo to Michael Glass concluded that they "…appear consistent with the law."

6. **Notification: The Department of Health shall notify parents of the specimen storage, retention and access policy and their rights under Chapter 70.02 RCW through the pamphlet "*Newborn Screening and Your Baby" (DOH***

publication 304-007) **that is included with the newborn screening specimen/information form.**

Rationale: Hospitals, clinics and other health care facilities that collect specimens for newborn screening are required to inform patients of their health care information practices (RCW 70.02.120) and typically include language in informed consent documents regarding specimens or biological samples that may be collected in the course of care. However, because the screening is not discretionary, and because the department of health maintains records, including the specimens, on those screened, a separate notification of practices is consistent with the intent of both the Uniform Health Care Information Act and the Governor's Executive Order 00-03. Further justification is provided by our finding that few health care facilities or parents are aware of our practices.

The pamphlet "Newborn Screening and Your Baby" (DOH publication 304-007) is specifically designed to provide parents with information about screening as required by WAC 246-650-020. A copy of this pamphlet is included with each specimen collection kit provided to health care providers and thus provides a convenient and effective method for informing parents of these policies.

Links to Electronic Resources

Washington State Legislation

- Health Care Information Act

(RCW 70.02)
http://www.leg.wa.gov/rcw/index.cfm?fuseaction=chapter&chapter=70.02&RequestTimeout=500
(ESSB5207)
http://www.leg.wa.gov/wsladm/billinfo/dspBillSummary.cfm?billnumber=5207

- Washington State Law Against Discrimination

(RCW 49.60)
http://www.leg.wa.gov/rcw/index.cfm?fuseaction=chapter&chapter=49.60&RequestTimeout=500
(WAC 162)
http://www.leg.wa.gov/wac/index.cfm?fuseaction=title&title=162

- Insurance Commissioner Rules

(WAC 284-43-720)
http://www.leg.wa.gov/wac/index.cfm?fuseaction=Section&Section=284-43-720
(WAC 284.84.100)
http://www.leg.wa.gov/wac/index.cfm?fuseaction=Section&Section=284-84-100
(RCW 48.44.023)
http://www.leg.wa.gov/RCW/index.cfm?fuseaction=section&section=48.44.023
(RCW 48.43.005)
http://www.leg.wa.gov/RCW/index.cfm?fuseaction=section&section=48.43.005

- Public Officers and Agencies, Release of Records for Research

(RCW 42.48)
http://www.leg.wa.gov/rcw/index.cfm?fuseaction=chapter&chapter=42.48&RequestTimeout=500

- Governor's Executive Order

EO 00-03
http://www.governor.wa.gov/eo/eo_00-03.htm

- Patient's Bill of Rights

(SB 6199)
http://www.leg.wa.gov/pub/billinfo/1999-00/senate/6175-6199/6199-s2_sl_03152000.txt

Federal Legislation/Regulations

- HIPAA

(Available in several electronic formats, choose the one you want to download)
http://aspe.hhs.gov/admnsimp/bannerps.htm

- 45 CFR 46

http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr46_99.html

- 21 CFR 50

http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr50_00.html

- 21 CFR 56

http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr56_00.html

- ADA

http://www.usdoj.gov/crt/ada/pubs/ada.txt

- Executive Order on Genetic Discrimination

http://usgovinfo.about.com/library/neo020800.htm

Other Resources

- NCSL Genetics Legislation Tables

http://www.ncsl.org/programs/health/genetics/charts.htm

- HIPAA Policy Guide Matrix

http://depts.washington.edu/hia (can be found under the “more information” section)

- Federal Policy and Legislative Activities

http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/fedlegis.html#ppolicy

- Association of State and Territorial Health Officials (ASTHO) Genetics Activities

http://www.astho.org/index.php?template=pubs.php

- California Health Care Foundation Report on Genetics and Privacy

http://www.chcf.org/topics/view.cfm?itemID=19759